COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

T01054 Determination of the symptoms of aspartame in subjects who have reported symptoms in the past compared to controls: a pilot double blind placebo crossover study.

Background

1. The FSA commissioned a double blind placebo controlled study of possible effects of aspartame in self reported aspartame sensitive individuals and controls. This item is being held in reserved session as it involves pre-publication results. This is important to ensure that the results can be published in the peer-reviewed literature. Once the research has been published, the finalised contractors' report and minutes of the COT discussion will be made public.

2. Previous studies investigating potential health effects of aspartame have been criticised for poor methodology, aspartame not being the focus of the study, or because they were funded by industry. To ascertain the feasibility and design for a definitive study, a pilot study was considered necessary to validate the methodology and the preparation used to administer aspartame. In addition this pilot study would allow a more extensive and comprehensive study to be powered appropriately.

3. Members had an initial discussion in March concentrating on the metabolomics investigations carried out on plasma and urine samples from the study. The protocol for the study and the patient information leaflet were in Annex 1 of COT 2010/10. A further verbal update was provided in July on the clinical observations and questionnaire. It was agreed that once these data were received, initial comments would be provided by a small group of Members. This feedback was provided in October and concentrated on statistical approaches and methodology related to the symptoms data.

4. The FSA has now received a draft paper on the study, which is at Annex 1. The researchers intend to submit for publication rapidly in order that peer reviewed results are published as soon as possible.

5. The European Food Safety Authority will complete their re-evaluation of aspartame in November..

Questions asked of the Committee

6. Members are invited to discuss the draft paper and then to advise on the following issues

i. the design of the study

ii. the results, particularly in relation to the comparison between self reported aspartame sensitive individuals and controls.

COT Secretariat
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